

Remarks

In response to the Office Action mailed February 28, 2003, Applicant respectfully requests reconsideration in view of the foregoing amendments and following remarks.

Applicant also wishes to thank the Examiner for carefully considering the application and finding that claims 1-25, 32, 35, 49 and 54-59 are directed to allowable subject matter.

The claims as presented are now believed to be in allowable condition.

Claims 1-59 were rejected under 37 C.F.R. §1.175(a)(1) for failure to identify a specific error, limitation, or addition relied upon to support the reissue application and objected to under 37 C.F.R. §1.172(a) for failure to establish assignee ownership interest in the patent for which reissue is being requested.

Further, claims 16-25 were rejected under 35 U.S.C. §112 as indefinite for failing to particularly point out and distinctly claim the subject matter regarded to be the invention. Claims 26-28, 30, 34, 36, 37, and 41 were rejected under 35 U.S.C. §102(e) as being anticipated by McPherson et al. or Russin. Claims 31 and 32 were rejected under 35 U.S.C. §102(b) as being anticipated by Chiou. Claims 26, 29, 36, 38-40, 42-48, and 50-54 were rejected under 35 U.S.C. §103(a) as unpatentable in view of Cibley or Chiou.

Reissue Declaration and Assignee Ownership

Enclosed with this response are an executed declaration specifically identifying an addition supporting this reissue application that satisfies the requirements of 37 C.F.R.

1.175(a)(1) and an executed Statement Under 37 C.F.R. § 3.73(b) establishing the right of assignee Paradigm Biodevices, Inc. to take action in the request for reissue of U.S. Patent

5,954,671. Consequently, the rejection and objections to claims 1-15 and 54-59 should be withdrawn. Accordingly, claims 1-15 and 54-59 are now in condition for allowance.

Amendments of Claims

A marked-up version of the claims is attached showing the changes made with the current amendment.

In view of the cancellation of claims 31, 34 and 37-48, and in view of the current application being a reissue application, claims 32, 33, 35, 36 and 49-59 have been renumbered as 31-44. Therefore, the dependent claims after claim 31 have been amended to account for the renumbering of claims.

Claim 4 has been amended to correct a minor error; the last step should refer to the "impactor cap" referred to in the previous step.

Claims 16, 18, 20, 21, and 24 have been amended to overcome Examiner's rejections under 35 U.S.C. §112 concerning the grammar of the claims. Claim 26 has been amended to distinguish the claimed embodiments from any device not comprising protruding arms over openings in the tip. Support for the amendment of claim 26 is found in Figures 6A and 6B and at column 4, lines 60-64 of the application.

Claims 32, 35, and 49 (as originally numbered in the reissue application) were amended to incorporate the limitations of their base claims: claims 31, 34 and 47, respectively. The examiner noted in the Office Action that claims 32, 35, and 49 would be allowable upon receipt of an appropriate declaration under 37 C.F.R §1.175(b)(1) and upon rewriting of the claims in independent form including all of the limitations of the base claim and any intervening claims. In view of the enclosed declaration and

amendments, the applicant submits that claims 32, 35, and 49 (now numbered as claims 31, 33 and 34) are in condition for allowance, along with the claims that depend therefrom.

Rejections under 35 U.S.C. §112

In view of the amendments to claims 16, 18, 20, 21, and 24 and the inclusion of an appropriate supplemental declaration under 37 C.F.R. §1.75(b)(1), applicant submits that claims 16, 18, 20, 21, and 24 are in condition for allowance. As claims 17, 19, 22, 23, and 25 depend from allowable claims, the claims 17, 19, 22, 23, and 25 are allowable for at least the same reasons.

Rejections under 35 U.S.C. §102(e) and §103(a)

McPherson et al. and Chiou as Prior Art

Applicant has amended claim 26 to require that the cutting tip contain protruding arms over openings. McPherson does not contain protruding arms. Instead, cutting edge 40 is defined by the termination of frusto-conical portion 38 (Figures 1-3 and column 3, lines 54-59). Chiou does not teach or suggest protruding arms over openings in the tip. Chiou describes cutting edge 35 of cannula 22 that can be jagged (column 3, lines 57-58). However, the jagged edge cannot protrude over the opening to lumen 36. If edge 35 did protrude, the edge would interfere with the coring and collection of the biopsy sample (column 4, lines 44-65).

In view of the lack of teaching or suggestion of arms protruding over the opening of a tip by McPherson and Chiou and the inclusion of an appropriate supplemental oath

under 37 C.F.R. §1.75(b)(1), the rejection of claim 26 should be withdrawn.

Accordingly, claim 26 is in condition for allowance. As claims 27-30 depend from claim 26, claims 27-30 are allowable for at least the same reasons.

In view of the foregoing amendments and remarks, this application is now in condition for allowance, and a notice to this effect is respectfully requested. If the Examiner believes, after this amendment, that the application is not in condition for allowance, the Examiner is invited to call the Applicants' attorney at the number listed below.

Respectfully submitted,



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May 27, 2003

02507/00101 246662

Marked-up version of claims showing changes

1ms B, 1. (Original) A method for harvesting bone through a guided delivery instrumentation system which operates through a percutaneous, laparoscopic, minimally-invasive technique, comprising the steps of:

making a small incision above a harvest site;

inserting an elongated guide wire with a blunt proximal end and a pointed distal end into the incision, distal end first, to a bone area to be harvested;

gently impacting the guide wire proximal end whereby the guide wire distal end enters into said bone area in the harvest site;

placing a cylindrical obturator with a generally cylindrical channel centrally formed within said obturator along its central longitudinal axis concentrically over the guide wire;

guiding the obturator onto to the guide wire toward the guide wire distal end whereby the obturator gradually splits muscle and tissue until it contacts said bone;

placing a first, hollow, cylindrical dilator concentrically over said obturator thereby increasing said incision to a percutaneous approach;

removing said guide wire and obturator;

placing an impactor cap over said first dilator;

gently tapping said first dilator with impactor cap into said harvest site bone;

inserting an elongated, hollow, cutting cylinder, said cutting cylinder having a handle on a proximal end and a hollow and a cutting tip on a distal end, into

aid first dilator whereby said cutting tip is brought into engagement with said bone;

cutting a portion of said bone with said cutting tip and bringing said cut portion

through the hollow cutting tip into the cutting cylinder;

removing the cutting cylinder and cutter tip from the first dilator;

removing the handle from said cutter cylinder;

removing the cut bone from the cutter cylinder;

removing the first dilator from said harvest site; and

closing the incision.

2. (Original) A method for harvesting bone as described in claim 1, further comprising the step of:

placing a second, hollow, cylindrical dilator concentrically over said first dilator.

3. (Original) A method for harvesting bone as described in claim 2, further comprising the step of:

placing a third, hollow, cylindrical dilator concentrically over said second dilator.

4. (Currently amended) A method for harvesting bone as described in claim 1, further comprising the steps of:

placing a hollow, cylindrical cannula having a proximal end and distal end, said

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distal end being longitudinally notched resulting in two protruding arms
parallel to the central axis of said cannula, concentrically over said dilator
whereby said cannula distal end engages the bone area;
placing an impactor cap over said cannula; and
gently tapping said cannula with impactor ~~impact~~ cap into said bone area.

5. (Original) A method for harvesting bone as recited in claim 4, further
comprising the step of:

placing a second, hollow, cylindrical dilator concentrically over said first dilator.

6. (Original) A method for harvesting bone as recited in claim 5, further
comprising the step of:

placing a third, hollow, cylindrical dilator concentrically over said second dilator.

7. (Original) A method for harvesting bone as recited in claim 4, further
comprising the steps of:

removing said dilator prior to insertion of said cutter cylinder; and

inserting said cutting cylinder into said cannula.

8. (Original) A bone harvesting apparatus for the removal of bone material
from a living body, comprising:

a guided delivery system, comprising:

an elongated guide wire having a pointed distal end and a blunt proximal end, said

distal end being adapted to engage a bone from which bone material is to be extracted;

a generally cylindrical obturator with an internal, hollow channel formed along an elongated central axis and positioned concentrically over said guide wire, said obturator having a generally dome-shaped distal end adapted to dividing tissue abutting said bone, and a proximal end with gripping means;

a generally cylindrical, hollow, open-ended dilator concentrically positioned over said obturator; and

a generally cylindrical, hollow, open-ended, forked cannula concentrically positioned over said dilator; and

a coring device within said delivery system for extracting precise amounts of bone material.

9. (Original) A bone harvesting apparatus as recited in claim 8, wherein said guided delivery system is further comprised of:

a plurality of generally cylindrical, hollow, open-ended dilators concentrically positioned over said obturator.

10. (Original) A bone harvesting apparatus as recited in claim 8, wherein: said dilator has a proximal end and a beveled distal end with teeth protruding therefrom.

11. (Original) A bone harvesting apparatus as recited in claim 10, wherein said coring device is comprised of:

a cutter cylinder having a proximal end and a distal end interconnected by a hollow tube;

a hollow cutting tip attached to said cutter cylinder distal end;

a handle joined to said cutter cylinder proximal end; wherein said cutter cylinder and cutting tip are adapted to fitting within said dilator.

12. (Original) A bone harvesting apparatus as recited in claim 10, wherein: said forked cannula has a proximal end terminating in two parallel, block-like elements, and a distal end longitudinally notched resulting in two longitudinally protruding arms parallel to a central, longitudinal cannula axis.

13. (Original) A bone harvesting apparatus as recited in claim 12, wherein said coring device is comprised of:

a cutter cylinder having a proximal end and a distal end interconnected by a hollow tube;

a hollow cutting tip attached to said cutter cylinder distal end;

a handle joined to said cutter cylinder proximal end;

wherein said cutter cylinder and cutting tip are adapted to fitting within said dilator.

14. (Original) A bone harvesting apparatus as recited in claim 11, wherein: said cutting tip has a proximal end joined to the cutter cylinder distal end and a distal end having two, protruding, generally triangular flat blades, each having two lateral

sides and a distal tip, said distal tips being connected to each other, each said blade lateral side being formed into a cutting edge, said cutting tip distal end also terminating in two cutting edges positioned between said protruding blades.

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15. (Original) A bone harvesting apparatus as recited in claim 13, wherein: said cutting tip has a proximal end joined to the cutter cylinder distal end and a distal end having two, protruding, generally triangular flat blades, each having two lateral sides and a distal tip, said distal tips being connected to each other, each said blade lateral side being formed into a cutting edge, said cutting tip distal end also terminating in two cutting edges positioned between said protruding blades.

16. (Currently amended) A method of harvesting bone, the method comprising:

inserting a guidance member through a percutaneous incision to a bone, at a bone harvest site;

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sequentially inserting ^{member of a set of} ~~a set of~~ at least one dilation ~~channels~~ channel through the incision ^{with} a first dilation channel of the set having been positioned over the guidance member;

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inserting a cutter device through ^{the} ~~a~~ member of the set of ~~at least one~~ dilation channels to engage the bone harvest site; and

cutting the bone with the cutter device to bring a portion of the bone into the cutter device's interior.

17. (Original) A method according to claim 16, the method further comprising:
making a percutaneous incision, that is at most 2 centimeters in length, above the bone harvest site.

18. (Currently amended) A bone harvesting apparatus, the apparatus comprising:
a guidance member adapted to engage a bone from which bone material is to be extracted;
a set of ~~a set of~~ at least one dilation channels *and* ~~a first dilation channel of the set~~
being adapted to be positioned over the guidance member; and
B ~~a cutter device adapted to be inserted into a member of the set of at least one~~
B dilation channels to engage the bone, the cutter device comprising a hollow collection shaft.

19. (Original) A bone harvesting apparatus according to claim 18, wherein the cutter device is disposable.

B 20. (Currently amended) A bone harvesting apparatus according to claim 18, wherein *at least one* ~~the~~ ~~a channel of the set of at least one dilation channels~~ is adapted to move in an arcing motion over the bone to permit the cutter device to harvest bone from more than one position.

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21. (Currently amended) A bone harvesting apparatus according to claim 18,
wherein ^{at least one} ~~the~~ channel of the set of at least one dilation channels comprises a pair of
members protruding from its distal end to position itself against the bone.

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22. (Original) A bone harvesting apparatus according to claim 21, wherein
one arm of the pair of members is longer than the other arm of the pair of members.

23. (Original) A bone harvesting apparatus according to claim 21, wherein
one arm of the pair of members is of equal length to the other arm of the pair of members.

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24. (Currently Amended) A bone harvesting apparatus according to claim 18,
wherein ^{at least one} ~~the~~ channel of the set of at least one dilation channels comprises means for
docking to the bone.

25. (Original) A bone harvesting apparatus according to claim 24, wherein the
means for docking comprises an arcuate sharp edge.

26. (Currently amended) A bone harvesting apparatus, the apparatus
comprising:

a collection shaft; and

a stainless steel cutting tip permanently attached to the collection shaft, the cutting tip comprising openings adapted to allow cut bone chips to move into the collection shaft's interior and two protruding blades.

27. (Original) An apparatus according to claim 26, wherein the cutting tip is bonded to the collection shaft.

28. (Original) An apparatus according to claim 26, wherein the cutting tip is mechanically fastened to the collection shaft.

29. (Original) An apparatus according to claim 26, wherein the cutting tip is ultrasonically welded to the collection shaft.

30. (Original) An apparatus according to claim 26, wherein the collection shaft comprises a biocompatible polycarbonate material.

31. (Currently Canceled) ~~A bone harvesting apparatus, the apparatus comprising:
a cutter device comprising, at the proximal end of a collection shaft, a depth gage that indicates a depth to which the cutter device has advanced into a patient's bone.~~

31. 32. (Currently amended) A bone harvesting apparatus according to claim 31, the apparatus further comprising:

a cutter device comprising, at the proximal end of a collection shaft, a depth gage

that indicates a depth to which the cutter device has advanced into a patient's

bone; and

calibration marks at the distal end of the collection shaft that indicate a volume of bone harvested.

32. 33. (Original) A bone harvesting apparatus according to claim 31, wherein the depth gage is readable when the cutter device is inserted into a dilation channel.

34. (Currently Canceled) ~~A method of harvesting bone, the method comprising:~~

~~creating a conduit from a patient's skin to a bone harvest site through a small~~

~~incision in the patient's skin;~~

~~expanding the diameter of the conduit by inserting, into the small incision, a~~

~~dilation channel; and~~

~~inserting a cutter device, comprising a hollow collection shaft, into the small~~

~~incision.~~

33. 35. (Currently amended) A method according to claim 34, wherein of harvesting bone, the method further comprises comprising:

creating a conduit from a patient's skin to a bone harvest site through a small incision in the patient's skin;

expanding the diameter of the conduit by inserting, into the small incision, a dilation channel;

inserting a cutter device, comprising a hollow collection shaft, into the small incision; and

expanding the diameter of the conduit by inserting a plurality of dilation channels of sequentially increasing size.

36. (Currently Canceled) ~~A method of harvesting bone, the method comprising:~~

~~docking a channel to a bone harvest site; and~~

~~inserting a bone harvesting device into the channel, the bone harvesting device comprising a hollow collection shaft.~~

37. (Currently Canceled) ~~A method of harvesting bone according to claim 36, the method further comprising:~~

~~moving the channel in an arc motion over the bone harvest site to permit the bone harvesting device to harvest bone from more than one position.~~

38. (Currently Canceled) ~~A method according to claim 36, wherein the channel comprises a pair of members protruding from its distal end to position itself against the bone harvest site.~~

39. (Currently Canceled) ~~A method according to claim 36, wherein the channel comprises means for docking to the bone harvest site.~~

a1 40. (Currently Canceled) ~~A method according to claim 39, wherein the means for docking comprises an arcuate sharp edge.~~

41. (Currently Canceled) ~~A method according to claim 36, wherein the channel is inserted through a percutaneous incision.~~

42. (Currently Canceled) ~~A method of harvesting bone, the method comprising:~~

~~inserting a hollow cylindrical coring device, comprising a permanently attached cutting tip, through a guided delivery system to engage a bone harvest site;~~

~~and~~

~~rotating the coring device in each of a clockwise and counterclockwise direction;~~

~~the rotation in each direction harvesting bone through the permanently attached cutting tip.~~

43. (Currently Canceled) ~~A method according to claim 42, wherein the cutting tip is bonded to the coring device.~~

44. (Currently Canceled) ~~A method according to claim 42, wherein the cutting tip is mechanically fastened to the coring device.~~

45. (Currently Canceled) ~~A method according to claim 42, wherein the cutting tip is ultrasonically welded to the coring device.~~

46. (Currently Canceled) ~~A method according to claim 42, wherein the hollow cylindrical coring device is inserted through a percutaneous incision.~~

47. (Currently Canceled) ~~A method of harvesting bone, the method comprising:~~

~~inserting a hollow cylindrical coring device, comprising a permanently attached cutting tip, through a guided delivery system to engage a bone harvest site;~~

~~and~~

~~directing a downward force on the coring device, the downward force engaging a downward facing cutting edge against the bone harvest site, the downward-facing cutting edge extending in a circumferential direction with respect to a circle in a plane perpendicular to a longitudinal axis defined by a shaft of the coring device.~~

48. (Currently Canceled) ~~A method according to claim 47, wherein directing a downward force on the coring device is performed in combination with rotating the coring device about the longitudinal axis.~~

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34. 49. (Currently amended) A method according to claim 47 of harvesting bone,
the method comprising:

inserting a hollow cylindrical coring device, comprising a permanently attached
cutting tip, through a guided delivery system to engage a bone harvest site;

and

directing a downward force on the coring device, the downward force engaging a
downward-facing cutting edge against the bone harvest site, the downward-
facing cutting edge extending in a circumferential direction with respect to a
circle in a plane perpendicular to a longitudinal axis defined by a shaft of the
coring device,

wherein the downward-facing cutting edge extends circumferentially around less
than a full circle.

35. 50. (Currently Amended) A method according to claim 47 34, wherein the
hollow cylindrical coring device is inserted through a percutaneous incision.

36. 51. (Currently Amended) A method according to claim 47 34, wherein the cutting tip is bonded to the coring device.

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37. 52. (Currently Amended) A method according to claim 47 34, wherein the cutting tip is mechanically fastened to the coring device.

38. 53. (Currently Amended) A method according to claim 47 34, wherein the cutting tip is ultrasonically welded to the coring device.

39. 54. (Original) A coring device for harvesting bone, the coring device comprising:

a hollow cylindrical shaft defining a longitudinal axis; and

a cutting tip permanently attached to the shaft, the cutting tip being configured to permit harvested bone to pass into the hollow cylindrical shaft and comprising:

two protruding blades joined at one end, each protruding blade comprising a

counterclockwise cutting edge and a clockwise cutting edge; and

two downward-facing cutting edges, each extending in a circumferential

direction with respect to a circle in a plane perpendicular to the shaft's

longitudinal axis.

40. 55. (Currently Amended) A coring device according to claim 39 54, wherein the cutting tip further comprises:

two support blades, each support blade comprising a counterclockwise cutting edge and a clockwise cutting edge and extending between a support section of the cutting tip and one of the protruding blades.

41. ~~56.~~ (Currently Amended) A coring device according to claim 39 ~~54~~, wherein the two protruding blades are at a 45° angle to the shaft's longitudinal axis.

42. ~~57.~~ (Currently Amended) A coring device according to claim 39 ~~54~~, wherein the cutting tip is bonded to the hollow cylindrical shaft.

43. ~~58.~~ (Currently Amended) A coring device according to claim 39 ~~54~~, wherein the cutting tip is mechanically fastened to the hollow cylindrical shaft.

44. ~~59.~~ (Currently Amended) A coring device according to claim 39 ~~54~~, wherein the cutting tip is ultrasonically welded to the hollow cylindrical shaft.